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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/928,272	09/12/1997	MICHAEL J. ISKRA	P-3818	9434

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EXAMINER

MATTER, KRISTEN CLARETTE

ART UNIT	PAPER NUMBER
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3771

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12/06/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 08/928,272	Applicant(s) ISKRA, MICHAEL J.	
	Examiner KRISTEN C. MATTER	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 5-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Action is in response to the Appeal Brief filed on 11/22/10. No claims have been amended, added or cancelled. Therefore, claims 1 and 5-9 are currently pending in the instant application.

In view of the Appeal Brief filed on 11/22/2010, **PROSECUTION IS HEREBY REOPENED**. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 5- 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burns (US 5,458,854) in view of Finney et al. (US 4,358,425, herein referred to as “Finney”).

Regarding claim 1, Burns discloses a one piece collection container assembly comprising an elongate tubular housing (12) having opposed first and second ends (see Figure 2), a solid partition (38) contacting a sidewall (22) of the tube forming a closed bottom (38) and positioned within said housing between the first and second ends (see Figure 2), said housing defining a volume for specimen collection and containment therein between said first end and said partition (see abstract), said second end forming a false bottom comprising a bottom end below said partition comprising an annular skirt (37) comprising an opening (47) therein.

The sole difference between Burns and the instant invention is the bottom of the tube being semi-spherical. However, absent a critical teaching and/or a showing of unexpected results from the tube having a semi-spherical bottom examiner contends that such a modification is an obvious design consideration to one of ordinary skill in the art as a mere change in shape that does not patentably distinguish an invention over the prior art. Changing the bottom to a semi-spherical shape would allow the tube to be compatible with common standard clinical equipment

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and instrumentation depending on the exact intended use of the tube. In addition, Finney teaches a specimen collection tube with a bottom surface through which fluid can pass and having a semi-spherical shape (see Figure 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Burns device with a semi-spherical false bottom as taught by Finney depending on the intended use of the device or to allow compatibility with standard clinical centrifuge equipment (abstract of Finney discusses how such a shape allows the tube to be used in the cavity of a centrifuge rotor) because such a shape was well known at the time of the invention. Such a modification would involve substitution of a well known method (i.e., tube having a semi-spherical bottom) into a well known device to yield predictable results that do not patentably distinguish an invention over the prior art.

Regarding claim 5, the partition disclosed by Burns is arcuate in shape and has at least a partially rounded bottom portion (see Figure 2).

Regarding claim 6, Burns lacks the partition being conical. However, absent a critical teaching and/or a showing of unexpected results from the partition being conical (as opposed to arcuate), examiner contends that such a modification is an obvious design consideration to one of ordinary skill in the art as a mere change in shape without a change in function that does not patentably distinguish an invention over the prior art. Furthermore, it appears as though the tube of Burns would work equally well with any shape of partition so long as specimen could be retained.

Regarding claims 7 and 8, Burns discloses the housing can be made of a thermoplastic polymer such as polyvinyl chloride (column 5, lines 43-50).

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Regarding claim 9, Burns is silent as to the dimensions of the container. However, absent a critical teaching and/or showing of unexpected results from making the container the claimed dimensions, examiner contends that it is an obvious design consideration to one of ordinary skill in the art to make the Burns container the claimed dimensions because those dimensions are commonly used for blood/specimen collection containers. In addition, it appears as though the device of Burns would perform equally well with the claimed dimensions. See also *In re Rose*, 220 F.2d 459, 463, 105 USPQ 237, 240 (CCPA 1955), in which the court held that mere changes in size do not patentably distinguish an invention over the prior art.

Claims 1 and 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dreier (US 5,038,958) in view of Saunders et al. (US 5,422,018, herein referred to as “Saunders”) and Finney.

Regarding claim 1, Dreier discloses a one piece collection container assembly comprising an elongate tubular housing (12) having opposed first and second ends (see Figure 2), a solid partition (11) contacting a sidewall of the tube (see Figure 2) forming a closed bottom (column 3, lines 5-10) and positioned within said housing between the first and second ends (see Figure 2), said housing defining a volume (16) for specimen collection and containment therein between said first end and said partition (see abstract and column 3, lines 5-10), said second end forming a false bottom comprising a bottom end below said partition (see Figures 1 and 2 and column 2, lines 65-68) comprising an annular skirt comprising an opening therein (see Figures 1 and 2). Even though Dreier discloses a vent (20) in the flange of the partition, the partition is still considered “solid” as defined by the instant specification (i.e., there is no specific definition)

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since the partition is made of a solid material that does not allow for the passage of liquid and no liquid is meant to pass through the hole for any reason in Dreier's disclosure (i.e., its sole use is for venting air as needed).

The sole difference between Dreier and the instant invention is the bottom of the tube being semi-spherical. However, Saunders discloses that centrifuge tubes are typically "flat or slightly rounded" (column 1, lines 14-16). Likewise, Finney discloses a centrifuge tube with a rounded, semi-spherical false bottom that allows the passage of liquid there through (see Figure 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have rounded the bottom end of Dreier as taught by Finney in order to allow the tube to work with "typical" laboratory equipment as taught by Saunders. Furthermore, there is nothing structurally in Dreier preventing the bottom from being rounded and it appears as though Dreier would perform equally well with any well known bottom surface shape (i.e., Dreier merely discloses the bottom surface as "preferably" allowing the device to stand upright and is therefore not a critical feature of the invention). Such a substitution appears to be the mere substitution of one typical tube shape for another to yield predictable results that do not patentably distinguish an invention over the prior art.

Regarding claim 5, Dreier lacks the partition being specifically arcuate. However, absent a critical teaching and/or a showing of unexpected results from the partition being arcuate (as opposed to conical), examiner contends that such a modification is an obvious design consideration to one of ordinary skill in the art as a mere change in shape without a change in function that does not patentably distinguish an invention over the prior art. Furthermore, it

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appears as though the tube of Dreier would work equally well with any shape of partition so long as specimen could be retained.

Regarding claim 6, the partition disclosed by Dreier is conical in shape and has at least a partially rounded bottom portion (see Figure 2).

Regarding claims 7 and 8, Dreier is silent as to the material of the tube other than being a molded plastic (column 3, lines 1-5). However, Saunders discloses that centrifuge tubes are commonly made of polyethylene or polypropylene (column 2, lines 50-55). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used polyethylene or polypropylene materials in Dreier's device since such materials are well known as suitable for use in centrifuge tubes as providing sufficient strength and flexibility. See also *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960), in which the selection of a known material based on its suitability for its intended use supported a prima facie case of obviousness.

Regarding claim 9, Dreier discloses a micro-centrifuge tube but states that the tube can be of "any reasonable size" (column 3, lines 5-10). Thus, absent a critical teaching and/or showing of unexpected results from making the container the claimed dimensions, examiner contends that it is an obvious design consideration to one of ordinary skill in the art to make the Dreier container the claimed dimensions because those dimensions are commonly used for blood/specimen collection containers in non-micro-scale centrifuge systems. In addition, it appears as though the device of Dreier would perform equally well with the claimed dimensions. See also *In re Rose*, 220 F.2d 459, 463, 105 USPQ 237, 240 (CCPA 1955), in which the court held that mere changes in size do not patentably distinguish an invention over the prior art.

Response to Arguments

Applicant's arguments filed 11/22/2010 have been fully considered but they are not persuasive.

In response to applicant's argument that one would not modify the shape of Burns because the cap of Burns would then not be able to be placed onto the bottom of the tube to allow it to stand upright, examiner contends that one of ordinary skill in the art would know how to also modify the cap of Burns to fit a rounded false bottom (i.e., by having an inner plug to fit in the smaller opening) if the feature of having the tube stand upright unsupported on a flat surface were desired in the modified device. Examiner also notes that there are standard centrifuges and tube holders that would allow the tube to stand upright even with a semi-spherical false bottom, which would allow the device to perform equally well as if set on a flat surface.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Here, as discussed above, changing the shape of Burns from a well known tube to a well known semi-spherical bottom is an obvious design consideration involving a mere change in shape that does not patentably distinguish an invention over the prior

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art because both shapes allow the tubes to work with standard laboratory equipment as demonstrated by Saunders.

Applicant's arguments involving Arlman are moot in view of the new grounds of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTEN C. MATTER whose telephone number is (571)272-5270. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761

/Kristen C. Matter/
Examiner, Art Unit 3771

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